

FDA 510(k), Premarket Notification : 510(k) Summary of Safety and Effectiveness Information

1.0 Submitter:

WEAR SAFE (MALAYSIA) SDN. BHD.
Lot PT 13726, Jalan Haji Salleh, Off Jalan Meru, 41050 Klang,
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2.0 Contact Person:

SEP 3 2010

Contact: Mr. Mohd Azlan
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Telephone No.: +603 3392 3088
Fax No.: +603 3392 2599

3.0 Name of Device:

Trade Name: Powder Free Natural Rubber Latex Examination Gloves, Blue Color,
Non-Sterile
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove.

4.0 Identification of The Legally Marketed Device:

Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile
Class I Patient Examination gloves, 80LYY, meets all of the requirements of ASTM D3578
Standard Specification for Rubber Examination Gloves.

5.0 Description of Device:

Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile will meet all
the current specification for ASTM D3578.

6.0 Intended Use of the Device:

Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile is a disposable device intended for medical purposes that is intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contaminants.

7.0 Summary of The Technological Characteristics of The Device:

Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D3578 - 05	Meets
Physical Properties	ASTM D 412 - 06ae1	Meets
Freedom from pin-holes	ASTM D 5151 - 06	Meets
Powder Free Residue	ASTM D 6124 - 06	Meets
Soluble Protein Level	ASTM D 5712 - 05	Meets
Biocompatibility	Dermal Sensitization (as per ASTM F720-81)	Not a contact skin sensitizer
	Primary Skin Irritation Test (as per 16CFR Part1500)	Not a primary skin irritant

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data that support a determination of substantial equivalence are described above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data are not needed for market cleared examination gloves.

10.0 Conclusion

It can be concluded that the Powder Free Natural Rubber Latex Examination Gloves, Blue Color, Non-Sterile is safe and effective for use and will perform according to the glove performance standards referenced in Section 7 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product.

Consequently, this device is substantially equivalent to current marketed devices.

This summary will include any other information reasonably deemed necessary by the FDA.

Prepared By : Mohd Azlan

Date : May 18, 2010



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Mohd Azlan
Quality Assurance Manager
Wear Safe (Malaysia) SDN. BHD.
Lot PT 13726, Jalan Haji Salleh, Off Jalan Meru
Klang, Selangor Darul Ehsan
Malaysia 41050

SEP 3 2010

Re: K101799

Trade/Device Name: Powder Free NR Latex Examination Gloves Blue (Colored), Non-Sterile, with Protein Labeling claim of 50 micrograms per dm² of glove or less of water soluble protein.

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LYY

Dated: August 20, 2010

Received: August 24, 2010

Dear Mr. Azlan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:

WEAR SAFE (MALAYSIA) SDN. BHD.

SEP 3 2010

510(k) Number (if known):

Device Name:

Powder Free NR Latex Examination Gloves Blue (Colored), Non-Sterile, with Protein Labeling claim of 50 micrograms per dm² of glove or less of water soluble protein.

Indication For Use:

A powder free latex examination glove is a disposable device made of natural rubber material intended to be worn on the hand for medical purposes to provide barrier against potentially infectious materials and other contaminants.

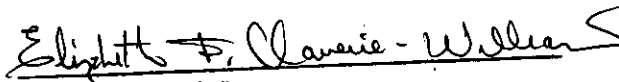
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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